

# Notice of Allowability

Application No.

10/049,692

Examiner

Blessing M. Fubara

Applicant(s)

LOUGHMAN, THOMAS CIARAN

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to communication of 07/15/02.
2. ☒ The allowed claim(s) is/are 1-7.
3. ☒ The drawings filed on 15 July 2002 are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☒ All b) ☐ Some\* c) ☐ None of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

## Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date 5/17/02, 6/20/02, 9/24/04
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material

5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_\_
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

*James M. Spear*  
JAMES M. SPEAR  
SENIOR EXAMINER  
AU 1615

### DETAILED ACTION

Examiner acknowledges receipt of request of change of correspondence address and associate power of attorney filed 07/19/04; preliminary amendment filed 07/15/02; IDS filed 09/21/04, 06/20/02 and 0/17/02.

### EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

The application has been amended as follows:

In set<sup>+</sup> the abstract provided on a separate sheet of paper.

#### *Allowable Subject Matter*

1. The following is an examiner's statement of reasons for allowance:

Kim et al. (US 5,552,520, cited in applicants specification) discloses the synthesis of BIM-23190 Somatostatin agonist (column 19, lines 20-30), which is compound A of the instant claims. Kim differs from the instant claims in that Kim does not disclose reacting BIM-23190, the somatostatin agonist with a polymer that comprises lactide, glycolide and tartaric acid units where compound A (BIM 23190) ionically bonds to the polymer.

Shalaby et al. (US 5,672,659) discloses a composition that comprises polyester that is ionically conjugated to a bioactive polypeptide (abstract). The polyester is a member selected from the group consisting of L-lactic acid, D-lactic acid, DL-lactic acid,  $\epsilon$ -caprolactone, p-dioxanone,  $\epsilon$ -caproic acid, substituted and unsubstituted trimethylene carbonate, 1,5-dioxepan-2-one, 1,4-dioxepan-2-one, glycolide, glycolic acid, L-lactide, D-lactide, DL-lactide, meso-lactide,

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alkylene oxalate, cycloalkylene oxalate, alkylene succinate, ( $\beta$ -hydroxybutyrate), and optically active isomers, racemates or copolymers of any of the above (column 1, line 55 to column 2, line 10). In Shalaby, the polyester is partially acid tipped with glutaric anhydride (column 2, lines 13-15). Somatostatin is one of the bioactive polypeptides that can ionically bond to the polyester and BIM-21003 is a somatostatin that is conjugated to d,l-lactide/glycolide/citric acid (column 2, line 29; column 12, lines 5-23) and in example 9, somatostatin tumor inhibiting analogue, BIM-23014 is conjugated to lactic/glycolide/malic copolymer. Shalaby differs from the instant claims in that Shalaby does not disclose a copolymer that contains tartaric acid; Shalaby does not also disclose the specific somatostatin derivative, BIM-23190; also, Shalaby does not disclose the ratio of glycolide to lactide that is recited by the instant claims; and Shalaby does not disclose the process of instant claim 1.

Culler et al. (US 6,268,342) discloses a composition that comprises somatostatin agonist, which has the structure of compound A of the instant claim (column 6, lines 35-45) and sustained release polymer such as lactic acid polymer or lactic-glycolic acid copolymer (column 10, lines 59-67). Culler differs from the instant claims in that Culler does not disclose that the polyester is ionically bonded to the somatostatin; Culler does not disclose that the polyester is tipped with tartaric acid and Culler does not teach the process of forming polyester-somatostatin ionic conjugate of the type recited in the instant claims.

Melmed et al. (US 5,972,893) discloses a method of treating hyperprolactinemia with a composition that contains somatostatin agonist (column 5, line 49) such as BIM-23190 (Examples 8 and 9) and when the composition is administered as a sustained release implant, the composition comprises lactic acid polymer or lactic acid co-glycolic acid copolymer (column 6, lines 51-60).

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Melmed differs from the instant claims in that Melmed does not disclose ionic conjugate of the somatostatin and the polyester; also the polymer of Melmed is not end tipped with tartaric acid.

The pending claims are thus allowable.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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### ABSTRACT OF THE DISCLOSURE

This invention pertains to a process for making a sustained release complex. Compound (I), which comprises Compound (A), having formula (A), and a copolymer comprising poly (l)-lactic-glycolic-tartaric acid (P (I) LGT), wherein the amino group of Compound (A) is ionically bound to a carboxyl group of the (P (I) LGT).

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